UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

006370

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

JAN - 6 1987

SUBJECT: EPA File Symbol 707-ERE(1)
Rally 40W Fungicide

EPA File Symbol 707-ERN(2)
RH-3866 Technical

EPA File Symbol 707-ERR(3)
Rally 60DF Fungicide

FROM: Deloris F. Graham DFG 1/22/87
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F 1/22/87

TO: Lois A. Rossi, Acting PM 21
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Registration Division (TS-767C)

APPLICANT: Rohm & Haas
Independence Mall West
Philadelphia, PA 19105

ACTIVE INGREDIENT:(1)
α-butyl-α-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile 40%
INERT INGREDIENTS: 60%

ACTIVE INGREDIENT:(2)
Azalkyl Triazole 92.0%
INERT INGREDIENTS: 8.0%

ACTIVE INGREDIENT:(3)
α-butyl-α-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile 60%
INERT INGREDIENTS: 40%

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BACKGROUND:

Submitted three acute oral studies on technical product, two acute dermal studies on Rally 40W Fungicide and data cited under EPA Registration No. 707-EUP-105. Acute Oral and Dermal studies submitted are under Accession No. 266077. Method of support not indicated.

RECOMMENDATION:

1. FHB/TSS finds all data except the acute oral study on RH-3866 Technical (81.1%) submitted acceptable to support formulation on which tested. In the acute oral study at least five animals per sex per dose must be used.

2. Since EPA Registration No. 707-EUP-105 (Systhane 40W Fungicide) is substantially similar to EPA File Symbol 707-ERE the data used to support the EUP can be used to support No. 707-ERE (Rally 40W Fungicide). Although the acute dermal data submitted under the EUP indicate CAUTION and under the formulated product indicates WARNING, it should be noted that the acute dermal on the formulated product was done by intra-peritoneal injection that produces an exaggerated sensitivity.

3. The complete acute toxicity battery with the exception of acute oral for EPA File Symbol 707-ERN (RH-3866 Technical) and the complete acute toxicity battery for EPA File Symbol 707-ERR (Rally 60DF Fungicide) must be submitted.

LABEL:

1. Labeling for EPA File Symbol 707-ERE should be synonymous to EPA File No. 707-EUP-105.

2. Labeling for the remaining two products (EPA File Symbol No. 707-ERN and 707-ERR) cannot be determined until acute toxicity data are submitted.

REVIEW:

(1) Acute Oral Toxicity Study on RH-53,866 Technical (81.1%): Rohm & Haas; Report No. 83R 0103; July 6, 1983.

PROCEDURE:

Five groups consisting of ten male rats each were dosed with one of the following concentrations: 0.0, 1.3, 2.0,

3.2, or 5.0 g/kg. Observations made for 14 days postdosing. Necropsy performed on all animals.

RESULTS:

At 1.3 g/kg, 1/10 M died; at 2.0 g/kg, 3/10 M died; at 3.2 g/kg, 5/10 M died; at 5.0 g/kg, 7/10 died. Toxic signs reported included brown-stained anal area, diarrhea, scant droppings, moribund, ataxia, red-stained muzzle, salivation, convulsion, abdominal breathing, yellow-stained anogenital area, prostration, and alopecia. Necropsy report revealed brown and/or yellow-stained anogenital area; matted fur on muzzle; red and/or tan-stained muzzle; reddened stomach mucosa and hair loss. LD_{50} reported to be between 0.5 and 5.0 g/kg.

STUDY CLASSIFICATION:

Core Supplementary Data. At least five animals per sex per dose must be used.

(2) Acute Oral Toxicity Study on RH-53,866 Technical (91.9%): Rohm & Haas; Report No. 85R 0247; May 22, 1986.

PROCEDURE:

Five groups consisting of ten female rats each were dosed with one of the following concentrations: 0.0, 1.3, 2.0, 3.2 or 5.0 g/kg. Observations made for 14 days postdosing. Necropsy performed on all animals.

RESULTS:

At 1.3 g/kg, 5/10 F rats died; at 2.0 g/kg, 5/9 F died and one animal died within 1 hour after dosing and was judged to have been misdosed and thoracic cavity fluid filled; at 3.2 g/kg, 9/10 F died; at 5.0 g/kg, 9/10 F died. Toxic signs reported included passiveness, prostration, moribund, ataxia, tremors, convulsions, salivation, abdominal breathing, decreased spontaneous motor activity, loss of righting, brown and/or yellow-stained anogenital area, tan-stained muzzle, diarrhea, anus reddened, scant droppings, arched back, and alopecia. Necropsy report revealed tan-stained muzzle; yellow-stained anogenital area; stomach filled with yellow fluid; reddened lungs; tan mottled areas on liver; brown stained abdomen; autolysis, carcass cannibalized, and alopecia. LD_{50} reported to be 1.36 g/kg.

STUDY CLASSIFICATION:

Core Guideline Data when used in conjunction with Report No. 86R 088A.

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TOXICITY CATEGORY: III- CAUTION.

(3) Acute Oral Toxicity Study on RH-53,866 Technical (91.9%): Rohm & Haas; Report No. 86R 088A;.August 14, 1986.

PROCEDURE:

Five groups consisting of ten male rats each were dosed with one of the following concentrations: 0.0, 1.3, 2.0, 3.2 or 5.0 g/kg. Observations made for 14 days. Necropsy performed on all animals.

RESULTS:

At 1.3 g/kg, 2/10 M died; at 2.0 g/kg, 4/10 M died; at 3.2 g/kg, 10/10 M died; at 5.0 g/kg, 10/10 M died. Toxic signs reported included passiveness, prostration, moribund, ataxia, tremors, convulsion, abdominal breathing, cool to touch, diarrhea; [redacted] brown-stained or yellow-stained anogenital area; scant droppings. Necropsy report revealed wet, tan or red-stained muzzle, yellow-stained anogenital area; stomach-yellow solid material; yellow fluid and distended; yellow fluid filled intestines; reddened intestines, and autolysis. LD_{50} reported to be 1.91 g/kg with confidence limits between 1.60 and 2.37 g/kg.

STUDY CLASSIFICATION:

Core Guideline Data when used in conjunction with Report No. 85R 0247.

TOXICITY CATEGORY: III - CAUTION.

(4) Acute Toxicity Study by Intraperitoneal Injection Using RH-3866 40WP: Rohm & Haas Company; Report No. 85R-126A; January 15, 1986.

PROCEDURE:

Nine groups consisting of ten male rats each were dosed intraperitoneally with one of the following concentrations: 0.0, 108, 158, 232, 341, 500, 734, 1077 or 1581 mg/kg. Observations made for 14 days postdosing. Necropsy performed on all animals.

RESULTS:

At 232 mg/kg, 1/10 M died, at 341 mg/kg, 3/10 M died; 500 mg/kg, 8/10 M died; at 734 mg/kg, 7/10 M died; at 1077 mg/kg, 10/10 M died; at 1581 mg/kg 9/10 M died. Toxic signs reported included passiveness, prostration, ataxia, convulsions,

red-stained eyes and muzzle, salivation, abdominal breathing, gasping, scant droppings, brown- and yellow-stained anogenital area; tan stained muzzle, diarrhea, lacrimation, distended abdomen, and vocalization. Necropsy report revealed wet, matted fur, tan brown or red-stained muzzle; brown or yellow-stained anogenital area; peritoneal cavity filled with tan fluid; stomach filled with brown fluid; intestines reddened, filled with brown fluid and distended; liver-dark, all lobes tan with granular appearance; kidneys dark; prominent Peyer's patches, autolysis; mesentery and intestines adhered together, liver, small intestine and pancreas adhered together, and subcutaneous mass. LD_{50} reported to be 456 mg/kg with confidence limits between 358 and 577 mg/kg.

STUDY CLASSIFICATION:

Core Guideline Data when used in conjunction with Report No. 85R 126B.

TOXICITY CATEGORY: II - WARNING.

(5) Acute Toxicity Study by Intraperitoneal Injection Using RH-3866 40WP: Rohm & Haas; Report No. 85R 126B; February 11, 1986.

PROCEDURE:

Same procedure used in Study No. 4 except all female rats used.

RESULTS:

At 108 mg/kg, 1/10 F died; at 158 mg/kg, 1/10 F died; at 341 mg/kg, 2/10 F died; at 500 mg/kg, 6/10 F died; at 734 mg/kg, 9/10 F died; at 1077 mg/kg, 9/10 F died; at 1581 mg/kg, /10 F died. Toxic signs reported included passiveness, prostration, ataxia, convulsion, red-stained eyes, red-stained muzzle, salivation, abdominal breathing, gasping, scant droppings, brown- and/or yellow-stained anogenital area, tan-stained muzzle, diarrhea, red-stained abdomen; distended abdomen and right eye partially closed. Necropsy report revealed wet, white or red-stained muzzle; red-stained eyes; yellow-stained anogenital area; tan or red fluid filled peritoneum; dark fluid filled stomach; intestines severely reddened and red fluid filled; prominent Peyer's patches on jejunum; liver - pale, tan granular area on all lobes; kidneys pale, cannibalization; liver, spleen, mesentery and intestines adhered, adrenal reddened and enlarged, uterine horns reddened and distended, and subcutaneous mass. LD_{50} reported to be 488 mg/kg with confidence limits between 367 and 660 mg/kg.

STUDY CLASSIFICATION:

Core Guideline Data when used in conjunction with Report No. 85R-126A.

TOXICITY CATEGORY: II - WARNING.

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Pages 7 through 11 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

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____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

__X__ A draft product label.

____ The product confidential statement of formula.

____ Information about a pending registration action.

____ FIFRA registration data.

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